1632/B

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November 27, 2002

Commissioner for Patents
Washington, D.C. 20231

Re: SN 09/888,233 "ASSAY FOR TOXIN INDUCED NEURONAL DEGENERATION AND VIABILITY IN *C. ELEGANS*" by Blakely, et al.
(Client Ref. VU0135)
Our Ref. VBLT:007US/10101121

Commissioner:

Enclosed for filing in the above-referenced patent application is:

(1) A Response to Restriction Requirement Dated October 3, 2002 And Request for Extension of Time;

(2) A check for $55.00 as the fee for the extension of time; and

(3) A return postcard to acknowledge receipt of these materials. Please date stamp and mail this postcard.

If the check is inadvertently omitted, or the amount is insufficient, or should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed materials, or should an overpayment be included herein, the Commissioner is authorized to deduct or credit said fees from or to Fulbright & Jaworski L.L.P. Account No.: 50-1212/VBLT:007US/SLH.

Very truly yours,

Priya D. Subramony
Agent for Applicants, Reg. No. 50,939

PDS/vv
Enclosure

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CERTIFICATE OF MAILING
37 C.F.R. 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231, on the date below:

November 27, 2002 — Date
Priya D. Subramony

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Blakely *et al.*

Serial No.: 09/888,233

Filed: June 22, 2001

For: ASSAY FOR TOXIN INDUCED NEURONAL DEGENERATION AND VIABILITY IN *C. ELEGANS*

Group Art Unit: 1632

Examiner: Peter Paras

Atty. Dkt. No.: VBLT:007US/SLH

RESPONSE TO RESTRICTION REQUIREMENT DATED OCTOBER 3, 2002 AND REQUEST FOR EXTENSION OF TIME

Commissioner for Patents
Washington, D.C. 20231

Commissioner:

This paper is submitted in response to the Restriction Requirement dated October 3, 2002, for which the date for response with a one-month extension of time is December 3, 2002.

In response to the restriction requirement which the Examiner imposed, Applicants elect, **with traverse**, to prosecute claims 15-16, 21-28 and 43-64, *i.e.*, **the Group II claims**, which are directed to methods of screening substances in a recombinant *C. elegans* that affect neuronal viability wherein the substance is a neuroprotective substance.

Traversal of the Restriction Requirement

The imposed restriction requirement has divided the invention into eleven groups as follows:

Group I – claim(s) 15-20, 27-28, and 43-64, drawn to a method of screening substances in a recombinant C. elegans that affect neuronal viability wherein the substance is a neurotoxic substance.

Group II – claim(s) 15-16, 21-28, and 43-64, drawn to a method of screening substances in a recombinant C. elegans that affect neuronal viability wherein the substance is a neuroprotective substance.

Group III – claim(s) 15-16, 27-30, and 43-64, drawn to a method of screening substances in a recombinant C. elegans that affect neuronal viability wherein the substance is a encoded by a polynucleotide.

Group IV – claim(s) 15-16, 31-32, and 43-64, drawn to a method of screening substance in a recombinant C. elegans that affect nueronal viability wherein the substance is polypeptide.

Group V – claim(s) 15-16, 33, and 43-64, drawn to a method of screening substances in a recombinant C. elegans that affect neuronal viability wherein the substance is a naturally occurring product.

Group VI – claim(s) 15-16, 34-39, and 43-64, drawn to a method of screening substances in a recombinant C. elegans that affect neuronal viability wherein the substance is a man-made chemical.

Group VII – claim(s) 15-16, 33, and 43-64, drawn to a method of screening substances in a recombinant C. elegans that affect neuronal viability wherein the substance is an environmental toxin.

Group VIII – claim(s) 65-77, drawn to a method of screening substances that can inhibit neuronal cell death.

Group IX – claim(s) 78-91, drawn to a method of screening substances to identify a substance that can be used for prevention and or therapy of neurodegenerative diseases.

Group X – claim(s) 92-98, drawn to a method of screening for substances that modulate dopamine transporter function.

Group XI – claim(s) 99-100, drawn to a method of screening for molecules that modulate neuronal signaling comprising screening molecules in a recombinant C. elegans that comprises neuronal cells that have mutated or knocked out neuronal signaling components.

Of these groups, Applicants contend that the claims classified by the Examiner into Groups I-VII should be examined together as drawn to screening methods for "substances" that "affect neuronal viability." This is reflected by the generic linking claims 15 and 16. The fact that the substances that are screened may be neurotoxic, neuroprotective, encoded by a polynucleotide, a polypeptide, naturally-occurring, man-made, or environmental toxins, does not split the basic screening method into different inventions. Thus, various types of substances, be they man-made, naturally-occurring, neurotoxic, neuroprotective, *etc.*, will be screened for their ability to affect neuronal viability using the *C. elegans* based screening method. It is clear to one of skill in the art, that the invention lies in the screening method as set forth in claim 15 and not in the type of substances that will be screened.

Applicants contend that such traversal is proper as the M.P.E.P., in §803, states that a restriction is only proper when:

> Under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP § 806.04 - § 806.04(i)) or distinct (MPEP § 806.05 - § 806.05(i)).
> **If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits,** even though it includes claims to independent or distinct inventions.

(**emphasis added**). This is also reiterated in M.P.E.P. §808.02(c) wherein it is stated that:

> **A different field of search**: Where it is necessary to search for one of the distinct subjects in places where no pertinent art to the other subject exists, a different field of search is shown, even though the two are classified together. The indicated different field of search must in fact be pertinent to the type of subject matter covered by the claims. Patents need not be cited to show different fields of search.
> **Where, however, the classification is the same and the field of search is the same and there is no clear indication f separate future classification and field of search, no reas ns exist for dividing among related inventions.**

(emphasis added). Thus, one of the criteria for a proper requirement for restriction between distinct inventions is the requirement of a serious burden on the Examiner. In this regard, Applicants further note that all the groups for which this traversal is made, *i.e.*, Groups I-VII, are classified in the same class and subclass, class 800 and subclass 3. Thus, there is no serious burden on the Examiner with regard to examination purposes. Therefore, Applicants contend that the examination of generic claims 15 and 16 should be done with generic "substances" including all the different substances outlined in the independent claims 17-64 as well. Applicants request that the inventions of Groups I-VII all be combined and this group be considered for examination. The Examiner is requested to consider the arguments above and send a communication to the undersigned with regard to this traversal.

The Examiner is invited to contact the undersigned patent agent at 512-536-3067 with any questions, comments or suggestions relating to the referenced patent application.

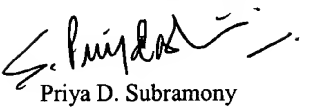
REQUEST FOR EXTENSION OF TIME

Pursuant to 37 C.F.R. § 1.136(a), Applicants petition for an extension of time of one month to and including December 3, 2002, in which to respond to the Restriction Requirement dated October 3, 2002.

Pursuant to 37 C.F.R. § 1.17, a check in the amount of $55.00 is enclosed, which is the process fee for a one-month extension of time.

If the check is inadvertently omitted, or should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed materials, or should an overpayment be included herein, the Commissioner is authorized to deduct or credit said fees from or to Fulbright & Jaworski Deposit Account No. 50-1212/VBLT:007US/SLH.

Respectfully submitted,



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Date: November 27, 2002